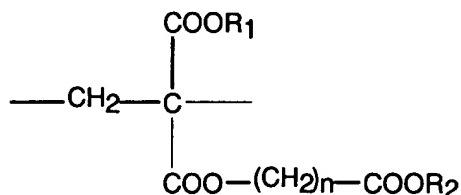


What is claimed is:

1. A pharmaceutical composition comprising:

a microparticle that includes a polymeric support material in which a substance can be dispersed, wherein the support material comprises at least about 50% w/w of at

5 least one homopolymer with a repeat unit according to Formula (I):



wherein

R₁ represents a C₁-C₆ alkyl group or a group (CH₂)_m-COOR₃ wherein m is an integer from 1 to 5 and R₃ is a C₁-C₆ alkyl group, R₁ and R₃ being the same or different;

10 R₂ represents a C₁-C₆ alkyl group the same or different from R₁ and R₃;

n is an integer from 1 to 5; and

at least one therapeutic agent that is encapsulated or dispersed in the polymeric support material of the microparticle.

15 2. A pharmaceutical composition according to claim 1 wherein:

R₁ and R₂ are independently chosen C₁-C₆ alkyl groups; and

n is 1.

3. A pharmaceutical composition according to claim 1 wherein:

20 the stated homopolymer comprising repeat units according to Formula (I) wherein

R₁ and R₂ are ethyl groups; and

n= 1.

4. A pharmaceutical composition according to claim 3, wherein the

25 composition being obtained by a single emulsification process.

5. A pharmaceutical composition according to any one of claims 1 to 4

wherein the support material comprises:

from about 90 to about 99.5% by weight of a homopolymer as defined in claims 1, 2, or 3; and

from about 0.5 to about 10% by weight of a polymer additive.

5 6. A pharmaceutical composition according to claim 5 wherein the polymer additive comprises at least one of polyethyleneoxide, polyvinylalcohol, polyvinylpyrrolidone, poly(N-2-hydroxypropyl methacrylamide), polyhydroxyethylmethacrylate, hydrophilic poly(aminoacid) such as polylysine or polysaccharide.

10

7. A pharmaceutical composition according to claims 5 and 6 wherein the polymer additive is a polyvinylalcohol. —

8. A pharmaceutical composition according to any one of claims 1 through 7
15 wherein the dispersed substance is hydrophobic. —

9. A pharmaceutical composition according to any one of claims 1 through 8 wherein the dispersed substance is a therapeutic agent that requires a solvation vehicle for administration.

20

10. A pharmaceutical composition according to any one of claims 1 through 7 wherein the dispersed substance is hydrophylic. ✓

11. A pharmaceutical composition according to any one of claims 1 to 10,
25 wherein the dispersed substance is a therapeutic agent. —

12. A pharmaceutical composition according to any one of claims 1 through 10 wherein the dispersed substance is a peptide or polypeptide. ✓

13. A pharmaceutical composition according to claims 1 through 12 wherein the dispersed substance is a protein.

14. A pharmaceutical composition according to any one of claims 1 through 13 wherein the dispersed substance is a bioactive molecule such as a drug, a therapeutic agent, an anticancer agent, a gene therapy agent, a plasmid DNA, a protein, an enzyme, a peptide, a radionuclide, a protein inhibitor, an analgesic, an anti-inflammatory agent, an antibiotic, an antiviral agent, an antineoplastic agent, a pyrimidine, purine or folic acid analog, an cytotoxic agent, an immunomodulator, a hormone, an antibody or a painkiller.

15. The pharmaceutical composition of Claim 14 wherein the pyrimidine analog is fluorouracil (5-FU).

16. A pharmaceutical composition according to any one of claims 1 through 15 wherein the dispersed substance is a bioactive molecule such as an anticancer agent or a gene therapy agent.

17. A pharmaceutical composition according to any one of claims 1 through 16 wherein the dispersed substance is a therapeutic agent for treating or reducing the severity of a urological disease or disorder.

18. A pharmaceutical composition according to any one of claims 1 through 17 wherein the dispersed substance is a therapeutic agent for bladder cancer.

19. A pharmaceutical composition according to any one of claims 1 through 18, wherein the dispersed substance is a taxane.

20. A pharmaceutical composition according to claim 19, wherein the taxane is paclitaxel, docetaxel (Taxotere®) or taxol®.

21. A method of preparing a pharmaceutical composition according to any one of claims 1 through 20 wherein the dispersed therapeutic is hydrophobic comprising the steps of:

- a) preparing a first solution in a volatile organic solvent wherein the solution comprises a polymeric support material and a therapeutic agent;
- b) preparing a second solution immiscible with the first solution, the second solution comprising a stabilizing agent;
- c) preparing an emulsion by combining the first and second solutions sufficient to produce a single phase being composed of a polymer solution; and
- d) evaporating the volatile organic solvent while stirring the emulsion to make the pharmaceutical composition.

22. A method of preparing a pharmaceutical composition according to any one of claims 1 through 20 wherein the dispersed therapeutic is hydrophilic comprising the steps of:

- a) preparing a first solution in a volatile organic solvent wherein the solution comprises a polymeric support material;
- b) preparing a second aqueous solution immiscible with the first solution, the second solution comprising a stabilizing agent and the therapeutic agent;
- c) preparing an emulsion by combining the first and second sufficient to produce a single phase being composed of a polymer solution; and
- d) evaporating the volatile organic solvent while stirring the emulsion to make the pharmaceutical composition.

23. A method according to claim 21 or claim 22, wherein the method comprises the addition steps:

- e) isolating the pharmaceutical composition by centrifugation; and
- f) washing the pharmaceutical composition with one or more wash cycles;

24. A method according to any one of claims 21 through 23 wherein the method comprises the addition step of:

(h) lyophilizing the microparticles.

5 25. A method according to any of claims 21 through 24, wherein the polymer support material is a poly(methylidene malonate 2.1.2).

26. A method according to any of claims 21 through 25, wherein the stabilizing agent is chosen from polyethyleneoxides, polysorbates, polyvinylalcohols, and
10 polymer additives described in claims 5 and 6.

27. A method according to any one of claims 21 through 26 wherein the stabilizing agent is a polyvinylalcohol.

15 28. Use of a pharmaceutical composition for the preparation of a medicament intended for the localized treatment of a disease or disorder wherein the pharmaceutical composition includes at least one microparticle according to claims 1 through 20 or prepared by a method according to claims 21 through 27.

20 29. Use of a pharmaceutical composition of any one of claims 1 through 20 for treatment of a urological disease or disorder.

25 30. The use of claim 29 wherein the pharmaceutical composition provides for controlled release of a therapeutic agent.

31. The use of claim 29 wherein the therapeutic agent to be delivered in a controlled release is an anticancer drug for the treatment of bladder cancer.

32. The use of claims 28 through 31 wherein the microparticles adhere to cells
30 of the tissue where the pharmaceutical composition was administered.

33. Use of a pharmaceutical composition of any one of claims 1 through 20 for treatment of cancer.

5 34. Use of a pharmaceutical composition of any one of claims 1 through 20 for treatment of bladder cancer.

35. A method of treating a subject suffering from or susceptible to a urological disease or disorder, comprising administering to the subject an effective amount of a
10 pharmaceutical composition of any one of claims 1 through 20.

36. A method of treating a subject suffering from or susceptible to cancer, comprising administering to the subject an effective amount of a pharmaceutical composition of any one of claims 1 through 20.

15 37. A method for treating a urological disorder comprising:
administering intravesically a microparticle with one or more encapsulated therapeutic agents to the lumen of the bladder, contacting the particles to the surface of the mucosa, releasing the encapsulated therapeutic agent in a controlled manner to treat
20 the urological disorder.

38. A method according to claim 37 wherein the microparticle comprises a poly(methylidene malonate 2.1.2) polymer support material.

25 39. A method according to claim 37 wherein the urological disorder is a cancer and the microparticle encapsulated therapeutic agent is an anticancer agent.

40. A method according to any one of claims 37 through 39 wherein the anticancer agent is a taxane.

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41. A method according to any to claim 40 wherein the taxane is paclitaxel, docetaxel (Taxotere®) or taxol®.

42. A method according to any one of claims 37 through 41, wherein
5 microparticles with encapsulated paclitaxel are used for intravesical chemotherapy of bladder cancer.

43. A method for the localized treatment of a disease or disorder comprising the steps of: administering a pharmaceutical composition according to claims 1 through
10 20 to the site of a disease or disorder, contacting the microparticles with the site, and releasing the encapsulated therapeutic agent in a controlled manner to treat the disease or disorder.

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